Public Health Service

COMMERCIAL EVALUATION LICENSE (CEL) AGREEMENT

Agreement made between the National Institutes of Health ("NIH"), the Centers for Disease Control ("CDC") or the Food and Drug Administration ("FDA"), hereinafter singly or collectively referred to as "PHS", agencies of the United States Public Health Service within the Department of Health and Human Services ("DHHS") through the Office of Technology Transfer, National Institutes of Health, Box OTT, Bethesda, MD 20892, USA and _____("LICENSEE"), a corporation of _____, having an office at _____ _____.

1. DEFINITIONS:

a. "Licensed Patent Rights" means US Patent Application(s) SN _____, entitled "_____" and filed on _____, 19___, and any US Patents issued from the patent application(s) listed above.

b. "Licensed Products" means the following biological materials, _____, including any progeny, subclones or derivatives thereof.

c. "Materials" means _____

_____.

2. LICENSEE wishes to obtain a license to evaluate the commercial applications of the Licensed Products and any inventions claimed in the Licensed Patent Rights.

3. LICENSEE intends to conduct laboratory experiments under this Agreement to evaluate the suitability for commercial development of inventions encompassed by the Licensed Patent Rights and the Licensed Products in the field of _____.

4. LICENSEE represents that it has the facilities, personnel and expertise to evaluate the commercial applications of the Licensed Products and the inventions encompassed by the Licensed Patent Rights, and that it will expend reasonable efforts and resources on research and development of potential commercial products using the Licensed Products and the inventions encompassed by the Licensed Patent Rights.

5. Pursuant to 35 USC §§167 and 207 and 37 CFR Part 404, PHS hereby grants to LICENSEE a nonexclusive license for evaluation purposes to make and use but not to sell the Licensed Products and products and processes encompassed within the scope of a claim in the Licensed Patent Rights. LICENSEE agrees that any commercial or industrial use or sale of any such products or processes, including any formalized in-house screening programs, other than for evaluation purposes, will be made only pursuant to the terms of a commercialization license to be negotiated in good faith by the parties. The rights provided herein are provided for the evaluation of commercial applications only and not for commercial use.

6. PHS agrees, after receipt of the payment required by paragraph 9, to provide LICENSEE with samples of the Materials, as available, and to replace such Materials, as available and at reasonable cost, in the event of their unintentional destruction.

7. LICENSEE agrees to retain control over the Licensed Products and the Materials, and not to distribute them to third parties without the prior written consent of PHS.

8. LICENSEE agrees that this Agreement does not preclude PHS from distributing the Materials or Licensed Products to third parties for research or commercial purposes.

9. In consideration of the grant in Paragraph 5, LICENSEE hereby agrees to pay the sum of US $_____ (_____ Dollars). Payment is due within thirty (30) days of LICENSEE's execution of this Agreement, and should be made by check or bank draft drawn on a United States bank made payable to "NIH/Patent Licensing."

All payments required by this Agreement shall be mailed to the following address: NIH, PO Box 360120, Pittsburgh, PA 15251-6120. Late charges will be applied to any overdue payments as required by the US Department of Treasury in the Treasury Fiscal Requirements Manual, Section 8025.40. The payment of such late charges shall not prevent PHS from exercising any other rights it may have as a consequence of the lateness of any payment.

10. This Agreement shall become effective on the date when the last party to sign has executed this Agreement and shall terminate _____ (___) months from its effective date. Upon termination LICENSEE shall return all Materials and Licensed Products to PHS or provide PHS with certification of their destruction, unless a commercialization license for the Application has been executed.

11. In the event that LICENSEE is in default in the performance of any material obligations under this Agreement, and if the default has not been remedied within ninety (90) days after the date of notice in writing of such default, PHS may terminate this Agreement by written notice.

12. LICENSEE acknowledges that third parties also may be evaluating the Licensed Patent Rights, the Licensed Products or the Materials for a variety of commercial purposes, and no guarantee can be made, should LICENSEE apply for an exclusive license, that one would be available for any particular field of use. PHS agrees to notify LICENSEE promptly if it receives from another company an exclusive license application in the field of use described in Paragraph 3.

13. LICENSEE is encouraged to publish the results of its research projects using the Licensed Products or the Materials. In all oral presentations or written publications concerning the Licensed Products or the Materials, LICENSEE will acknowledge the contribution by the named inventors of the Licensed Products or the Materials, unless requested otherwise by PHS or the named inventors.

14. LICENSEE agrees to submit in confidence a final report to PHS within thirty (30) days of termination of this Agreement outlining in general its results of commercial evaluation of the Licensed Patent Rights, the Licensed Products and the Materials provided by this Agreement.

15. PHS agrees, to the extent permitted by law, to treat in confidence for a period of three (3) years from the date of disclosure any of LICENSEE's written information about the Licensed Patent Rights, the Materials or Licensed Products that is stamped "CONFIDENTIAL" except for information that was previously known to PHS, or that is or becomes publicly available, or that is disclosed to PHS by a third party without an obligation of confidentiality.

16. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE FITNESS FOR ANY PURPOSE OF THE MATERIALS OR LICENSED PRODUCTS PROVIDED TO LICENSEE UNDER THIS AGREEMENT, OR THAT THE LICENSED PATENT RIGHTS MAY BE EXPLOITED WITHOUT INFRINGING OTHER PATENT RIGHTS. LICENSEE accepts license rights to the Licensed Patent Rights, the Licensed Products and the Materials "as is," and PHS does not offer any guarantee of any kind.

17. LICENSEE agrees to indemnify and hold harmless PHS and the United States government from any claims, costs, damages or losses that may arise from the practice of the Licensed Patent Rights or through the use of the Licensed Products or the Materials.

18. Neither party shall have any obligation with respect to the other if any applicable patent rights are infringed by a third party.

19. LICENSEE agrees in its use of any PHS-supplied materials to comply with all applicable statutes, regulations and guidelines, including Public Health Service and PHS regulations and guidelines. LICENSEE agrees not to use the Materials or the Licensed Products for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. LICENSEE agrees not to use the Materials or Licensed Products for research involving human subjects or clinical trials outside of the United States without notifying PHS, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to PHS of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

20. This Agreement shall be construed in accordance with the laws of the United States as interpreted and applied by the Federal courts in the District of Columbia.

21. This Agreement constitutes the entire understanding of PHS and LICENSEE and supersedes all prior agreements and understandings with respect to the Licensed Patent Rights, the Materials and the Licensed Products.

22. The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions of this agreement.

23. Paragraphs 13, 15, 16, and 17 of this Agreement shall survive termination of this Agreement.

SIGNATURE PAGE

In Witness Whereof, the parties have executed this agreement on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

FOR PHS:

_____ Date _____
Barbara McGarey, JD
Deputy Director
Office of Technology Transfer
National Institutes of Health

Mailing Address for Notices: Office of Technology Transfer National Institutes of Health, Box OTT, Bethesda, MD 20892

FOR LICENSEE:

(The undersigned expressly certifies or affirms that the contents of any statements of LICENSEE made or referred to in this document are truthful and accurate.)

Signature _____ Date _____

Printed Name _____

Title _____

Mailing Address for Notices:
_____

_____

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